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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/888,202	07/07/1997	JULIO L. PIMENTEL		1919

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MARSHALL O'TOOLE GERSTEIN
MURRAY & BORUN
6300 SEARS TOWER
233 WACKER DRIVE
CHICAGO, IL 60606

EXAMINER
UNGAR, SUSAN NMN

ART UNIT	PAPER NUMBER
1642	31

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
08/888,202	Pimentel
Examiner	**Art Unit**
Ungar	1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Jul 2, 2002* .

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1, 8, 14, 18, 31, and 38* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1, 8, 14, 18, 31, and 38* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The Amendment filed July 2, 2002 (Paper No. 30) in response to the Office Action of January 2, 2002 (Paper No. 28) is acknowledged and has been entered. Previously pending claims 1, 8, 38 have been amended, claim 39 has been canceled. Claims 1, 8, 14, 18, 31, 38 are currently under prosecution.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. The following rejections are being maintained:

Claim Rejections - 35 USC § 103

4. Claims 1, 8, 14, 18, 31, 38 remain rejected under 35 USC 103 for the reasons previously set forth in Paper No. 28, Section 5, pages 2-6 and the previous rejections cited in Paper No. 28, Section 5, pages 2-6)..

Applicant (1) reiterates the legal standards for an obviousness-type rejection and concludes with MPEP 2144.09 wherein it is stated that *a prima facie* case of obviousness can be rebutted by evidence of superior or unexpected results, (2) reviews the art of record drawn to the instant rejection.

Applicant's review of the references has been considered as follows:

Examiner agrees with Applicant's summary of US 4,598,089.

As drawn to the review of Moloney - Applicant stresses that the reference is drawn to decreasing body fat accretion by destroying existing fat cells by cytotoxic antibodies. However, the issue raised with Moloney was not drawn to cytotoxic antibodies or to a method of decreasing body fat accretion by destroying existing fat cells since the '089 reference recites a method of inhibiting fat absorption by inhibition of lipase, but rather that Moloney was sited because it specifically teaches

the usefulness of a method for reducing fat content of meat and teaches that immunological methods are being used to decrease fat content of meat and that future developments of the technology requires the identification of specific antigenic determinants and their use an antigens to increase the efficiency of lean meat production without adverse effects on animal welfare or meat quality.

As drawn to the review of Flint et al, Applicant stresses that the antibodies produced were found to be cytotoxic at high concentrations and that different types of administration had different effects. However, the issue raised with Flint was not drawn to cytotoxic antibodies but rather to the teaching of the importance of reducing fat content in domestic species and the teaching that one strategy for reducing adiposity could involve the immunoneutralizaiton of GI substances that have direct lipogenic effects on adipose tissues. Applicant refers to Futter and Flint, Hu et al and Thorton and Tume, 1987, reviewed in Moloney, however, since these references have not been submitted, it is not possible for Examiner to consider the arguments drawn to these references, especially since the reference was not cited for the method used in the reference.

Applicant argues as drawn to the combination of '089 and Moloney or the Modification of '089 with Moloney, that the method of Moloney and the mechanism by which it acts is different than the instantly claimed invention. The argument has been considered but has not been found persuasive because, for the reasons set forth above, the reference was not cited for the method, but because it specifically teaches the usefulness of a method for reducing fat content of meat and teaches that immunological methods are being used to decrease fat content of meat and that

future developments of the technology requires the identification of specific antigenic determinants and their use an antigens to increase the efficiency of lean meat production without adverse effects on animal welfare or meat quality. Further, Applicant is arguing the references without clearly addressing all of the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant argues, as drawn to Flint, that the reference is drawn to a method different than that of the instantly claimed invention. The argument has been considered but has not been found persuasive because, for the reasons set forth above, the reference was not cited for the method but rather because it specifically suggests that one strategy for reducing adiposity could involve the immunoneutralizaiton of GI substances that have direct lipogenic effects on adipose tissues. Further, Applicant is arguing the references without clearly addressing all of the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention

fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant argues as drawn to the combination of '089 and Moloney and Flint or Modification of '089 with Moloney and Flint, that the references teach a method and the mechanism by which it acts is different than the instantly claimed invention. The argument has been considered but has not been found persuasive for the reasons set forth above. Further, Applicant argues that one of skill in the art would not be motivated to modify the method of '089 by substituting antibodies to adipose tissue plasma membranes. This argument has been considered but has not been found persuasive because Applicant is arguing the references without clearly addressing all of the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant argues as drawn to Ohkaru et al that there is no disclosure of *in vivo* activity of the monoclonal antibodies, only one antibody inhibited, no

disclosure of administration of the monoclonal antibodies and no disclosure of oral administration of the antibodies. There is no indication that the particular antibodies would retain activity or be effective and there is no indication of how the monoclonal antibodies were raised.

The arguments have been considered but have not been found persuasive because Applicant is arguing the references without clearly addressing all of the combined teachings. It must be remembered that the references are relied upon in combination and are not meant to be considered separately as in a vacuum. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant argues as drawn to the combination of '089 and Moloney and Flint and Ohkaru or Modification of '089 with Moloney and Flint and Ohkaru, that even if overly simplistic logic that a drug that inhibits pancreatic lipase and an antibody which inhibits pancreatic lipase are components that a functional equivalents, equivalency must be recognized in the prior art and Applicant cites MPEP 2144.06. Examiner has not provided an factual evidence or technical logic that these two agents are recognized in the art as equivalents for the same purpose. The argument has been considered but has not been found persuasive because a review of *In re Ruff*, 256 F.2d 590, 118 USPQ 340 (CCPA 1958) reveals that the case is drawn to

the question of whether or not Applicant's own admission of equivalency can be used to support a rejection under 35 USC 103. Although the Court states that

"That two things are actually equivalents, in the sense that they will both perform the same function, is not enough to bring into play the rule that when one of them is in the prior art the use of the other is obvious and cannot give rise to patentable invention."

The court also states that

The "question of equivalence.....is a special aspect of what amounts to patentable "invention assuming novelty to exist. The statutory provision on this subject is 35 USC 103 and the test there laid down is simply whether the difference between what is claimed and the prior art would have been obvious to one of ordinary skill in the art at the time the invention was made".

In the instant case, the invention is obvious for the reasons previously set forth given that motivation existed for inhibiting pancreatic lipase, a method existed to inhibit the lipase, antibodies were known that inhibited lipase, and antibodies were conventionally and successfully used in animal feed, orally administered for reasons of animal husbandry. It does not appear that the other cases cited in the MPEP section are relevant to the instant rejection other than *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982) which specifically states that "An express suggestion to substitute one equivalent component or process for another is not necessary to render such substitution obvious." Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant further argues that the proposed substitution is complicated by the recognition in the art that *in vivo* vs *in vitro* delivery and activity of agents may

differ and oral versus other modes of administration may provide differences. The arguments have been considered but have not been found persuasive for the reasons previously set forth drawn to the combined references. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant argues JP 02150294 individually. The argument has been considered but has not been found persuasive for the reasons previously set forth drawn to the combined references. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

As drawn to the combination of '089 and Moloney and Flint and JP 02150294 or Modification of '089 with Moloney and Flint and JP 02150294. Applicant reiterates arguments drawn to MPEP 2144.06. The arguments have been considered but have not been found persuasive for the reasons set forth above. Further, the arguments have been considered but have not been found persuasive for

the reasons previously set forth drawn to the combined references. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant states that it appears that the US 5,585,098 reference was withdrawn in Paper No. 17. However, contrary to Applicant's statement, a review of Paper No. 17 does not reveal that US 5,585,098 was withdrawn. On Page 2, Section 3, the claims were rejected under 35 USC 103 for the reasons previously set forth in Paper No.13, paper No. 8, Paper No. 5 which included the US 5,585,098 reference. Further, newly added claims 38 and 39 were rejected under 35 USC 103 in Section 4, page 5 wherein US Patent No. 5,585,098 was specifically cited.

Applicant argues that the orally administered antibody is actually broken down in or on the way to the intestine and maintain the desired effect because the variable portion of the antibody makes it to the desired location which supports the Atkinson Declaration which expressed surprise as to the retained activity of the antibodies in the present invention. The argument has been considered but has not been found persuasive because it is not the Fc portion of the anti lipase antibody but rather the variable region which is critical to the invention. The reference clearly showed the successful oral administration of chicken antibodies and the Atkinson Declaration is not persuasive for the reasons previously set forth. Further, the

arguments have been considered but have not been found persuasive for the reasons previously set forth drawn to the combined references. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant argues US 5,080,895 individually. The argument has been considered but has not been found persuasive for the reasons previously set forth drawn to the combined references. It is the combination of all of the cited and relied upon references which made up the state of the art with regard to the claimed invention. Applicant's claimed invention fails to patentably distinguish over the state of the art represented by the cited references taken in combination. In re Young, 403 F.2d 754, 159 USPQ 725 (CCPA 1968); In re Keller 642 F.2d 413,208 USPQ 871 (CCPA 1981). Applicant's arguments have not been found persuasive and the rejection is maintained.

Applicant reiterates arguments drawn to the Atkinson Declaration and cites Rawn, Biochemistry. The arguments have been considered but have not been found persuasive for the reasons previously set forth. Further, the Rawn reference has not been submitted and therefore the argument could not be evaluated. Applicant's arguments have not been found persuasive and the rejection is maintained.

Claim Rejections - 35 USC § 112

5. Claims , 8, 14, 18, 31, 38 arerejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 28, Section 8, pages 8-9.

Applicant argues that (a) since page 3, line 8 states teaches that lipase is an enzyme produced by the pancreas and that since other lipases are not produced by the pancreas, one of skill would know that references to lipase in the specification and claims refer to pancreatic lipase, (b) p. 4 describes an antigen, swine pancreatic extract that contains lipase and the antibody produced against this antigen must be an antibody to pancreatic lipase.

The arguments have been considered but have not been found persuasive because (a') page 3 does not state that the term "lipase" is limited to pancreatic lipase. This is crucial since other types of lipases are well known. Further, (b') page 4 states only that pancreatic lipase is a preferred antigen and again does not limit to pancreatic lipase. Finally, a review of the Example section demonstrates that the specific antibody was prepared by injection of lipase (Sigma Chemical) into chickens (p. 5). The specification does not teach the injection of pancreatic lipase to produce the antibodies. Applicant's arguments have not been found persuasive and the rejection is maintained.

New Grounds of Objection

6. The amendment filed July 20, 2002 is objected to under 35 U.S.C. § 132 because it introduces new matter into the specification. 35 U.S.C. § 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows:

"By inhibiting lipase through binding the ingested fat will not be absorbed and the fat itself will be excreted".

The newly added amendment is indefinite as it is not clear whether binding is to the ingested fat or to the lipase. Further, the newly added matter broadens the scope of the specification as originally filed since the basis for the amendment is found only in claim 3 (see Paper No. 28, page 7, Section (2)), and is drawn only to antibody binding which inhibits lipase activity in the gastrointestinal tract. Applicant is required to cancel the new matter in the response to this Office action.

7. All other objections and rejections recited in Paper No. 28 are withdrawn.

8. No claims allowed.

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A SHORTENED STATUTORY PERIOD FOR RESPONSE TO THIS FINAL ACTION IS SET TO EXPIRE THREE MONTHS FROM THE DATE OF THIS ACTION. IN THE EVENT A FIRST RESPONSE IS FILED WITHIN TWO MONTHS OF THE MAILING DATE OF THIS FINAL ACTION AND THE ADVISORY ACTION IS NOT MAILED UNTIL AFTER THE END OF THE THREE-MONTH SHORTENED STATUTORY PERIOD, THEN THE SHORTENED STATUTORY PERIOD WILL EXPIRE ON THE DATE THE ADVISORY ACTION IS MAILED, AND ANY EXTENSION FEE PURSUANT TO 37 C.F.R. § 1.136(a) WILL BE CALCULATED FROM THE MAILING DATE OF THE ADVISORY ACTION. IN NO EVENT WILL THE STATUTORY PERIOD FOR RESPONSE EXPIRE LATER THAN SIX MONTHS FROM THE DATE OF THIS FINAL ACTION.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703) 305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
July 30, 2002